

Serial No. 09/717,894

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### REMARKS/ARGUMENTS

Claims 1-10 as amended are in the application. Claims 1 and 2 have been amended to overcome the rejections under 35 USC §112. Reconsideration of the application and reexamination of the claims as amended are respectfully requested in view of the claim amendments and the arguments that follow.

### CLAIM REJECTIONS UNDER 35 USC §112

The Examiner has rejected claims 1-10 under 35 USC §112 second paragraph as being indefinite in that the use of the term "technical triglyceride" is unclear. Applicants have rewritten claims 1 and 2 to remove the term "technical". The claims as amended now recite "triglyceride" the meaning of which is defined on page 3, lines 16-27 in the instant specification.

The Examiner alleges that Claims 1-10 are incomplete because they fail to recite a recovery step for the product produced. The Examiner further alleges that since the claims do not recite a recovery step, they fail to particularly point out and distinctly claim the complete process. Applicants traverse this rejection by pointing out that, contrary to the Examiner's position, it is clear from the record that the product of the claimed process need not be isolated. The instant specification makes it clear that the product produced, which is a triglyceride having a low acid number, is meant to be further processed "as is" without a purification step at page 1, lines 25-28 with the disclosure that the free fatty acids in fats containing relatively great amounts of free fatty acids ".....have been found to be troublesome in the various **processes used for further processing** of the triglycerides, more especially in the low-pressure transesterification process for the production of fatty acid methyl esters." (emphasis added).

The Examiner has rejected claim 2 as being vague and indefinite for the use of "about" in the context of the number of carbon atoms. Applicants overcome this rejection by amending claim 2 to remove the term "about".

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### CLAIM REJECTIONS UNDER 35 USC § 103(a)

The Examiner has rejected claims 1-10 under 35 USC §103(a) as being obvious over Gatfield et al taken with Lepper et al. The Examiner alleges that Gatfield teaches a method of treating the triglyceride, Stillingia oil, with lower alkanols such as ethanol to intrinsically produce a pre-esterification product having a lower acid number. The Examiner further states that it can be reasonably concluded from Lepper that the transesterification reaction of a triglyceride or oil with a short chain monoalcohol using a suitable catalyst will result in a product having a lower acid value. The Examiner concludes that one skilled in the art would have reasonably expected at the time that the invention was made that the pre-esterification product is subjected to further biotransformation using lipase with similar results, since the reactions are substantially similar and differ only in the catalyst used.

Applicants overcome this rejection by pointing out that the Gatfield reference teaches the enzymatic transesterification of the glyceryl esters of trans-2,cis-4-decanedioic acid (DDA) in Stillingia oil using *Candida antarctica* in the presence of ethanol. Gatfield contains no teaching about the direct esterification of free fatty acids with lower alkanols such as ethanol in the presence of an enzyme. Thus, Gatfield is deficient in that it does not teach or suggest the substitution of direct esterification for transesterification using an enzyme catalyst. Lepper does not remedy the deficiencies of Gatfield because Lepper teaches direct esterification of the free fatty acids present in the triglyceride with a short-chain monoalcohol using an acidic catalyst. This esterification stage is carried out in the presence of an entraining agent which is liquid under the process conditions and substantially immiscible with the oil phase.

Taken together, the teachings of the references cited by the Examiner do not render Applicants claims obvious for the following reasons. Gatfield teaches transesterification of DDA glycerides using an enzymatic catalyst. Lepper teaches esterification of the free fatty acids present in a triglyceride with a short-chain

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monoalcohol using an acid catalyst. Neither Gatfield nor Lepper teach the interchangeability of acidic and enzymatic catalysts in direct esterifications and transesterifications. Lepper teaches that certain enzymes that are effective catalysts in direct esterifications are not effective catalysts in transesterifications (column 1, lines 54-57). A fair reading of Lepper leads to the conclusion that the choice of an enzyme catalyst for a direct esterification, a transesterification or ester hydrolysis is the result of trial and error rather than predictability based on scientific principles. The following excerpts from the Lepper reference illustrate this point. *"Our own attempts to liberate the DDA by hydrolysis of the ester bond using esterases and lipases either failed completely or gave very small yields of the desired acid. The esterases and lipases tested thus evidently had too low a specificity with respect to DDA."* (column 1, lines 38-41); *"Our own attempts to form the ethyl ester via an enzymatic transesterification by means of the usual lipases and esterases were also unsuccessful, probably because of their lack of specificity."* (column 1, lines 43-45); *"Further attempts with lipase PS from Pseudomonas species (Amano) and lipase B from Candida cylindracea (Biocatalysts) were also unsuccessful. The two enzymes are otherwise extremely suitable for esterifications. ."* (column 1, lines 54-57); *"Further attempts with the lipases of Pseudomonas fluorescens, Chromobacterium viscosum and pancreatic lipase also failed. ."* (column 1, lines 61-63). From the foregoing it is clear that Lepper does not teach or suggest that any enzyme will function as a catalyst in a specific esterification reaction. Thus, one of ordinary skill in the art would not be motivated to replace an acidic catalyst with an enzyme in an esterification reaction because there is no reasonable expectation of success in doing so.

Applicants also respectfully submit that there is no basis for the Examiner's assertion that the treatment of Sillingia oil with a lower alkanol in the presence of an enzyme intrinsically produces a pre-esterification product having a lower acid number. The teachings of Lepper concerning the unpredictability of the ability of an enzyme to catalyze a direct esterification or a transesterification as shown above make it clear that

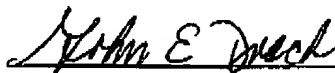
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the Examiner has not provided a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic (the production of a pre-esterification product having a lower acid number) necessarily flows from the teachings of the applied art as required by MPEP 2112. .

The above arguments overcome the Examiner's case of prima facie obviousness based on the contention that since both Lepper and Gatfield teach a pre-esterified product produced by means of a catalyzed direct esterification of the free fatty acids present in a triglyceride differing only in the catalyst used, it would be obvious to optimize the result-effective variables in Lepper and Gatfield.

It is believed that the foregoing reply is completely responsive under 37 CFR 1.111 and that all grounds of rejection and objection have been completely overcome or obviated. It is believed that the claims 1-10 are now in condition for allowance and a notice of allowance is respectfully requested.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Claims 1 and 2 have been amended as follows:

1. (Amended) A process for the production of deacidified fats and/or oils comprising the steps of:
  - (a) reacting a [technical] triglyceride having an acid value of up to about 60 and an excess of a lower alcohol having from 1 to 4 carbon atoms and an effective amount of a lipase to form a pre-esterification product having an acid value of from about 0.5 to about 10,
  - (b) optionally removing water and unreacted alcohol from the pre-esterification product,
  - (c) further reacting the pre-esterification product from step (a) or (b) with additional lower alcohol to form a post-esterification reaction product having an acid value of from about 0.1 to about 0.5.

2. (Amended) The process of claim 1 wherein the [technical] triglyceride is a compound of the formula (I):



wherein each of  $\text{R}^1\text{CO}$ ,  $\text{R}^2\text{CO}$  and  $\text{R}^3\text{CO}$  is a linear and/or branched, saturated and/or unsaturated acyl group having from 6 to 24 carbon atoms and having up to 3 double bonds.